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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/728,973 | 12/04/2000 | Nick N. Nguyen | ASP-7 | 3999 |

26285 7590 12/23/2008

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| EXAMINER | |
|---|---|
| CHORBAJI, MONZER R | |
| ART UNIT | PAPER NUMBER |
| 1797 | |
| MAIL DATE | DELIVERY MODE |
| 12/23/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/728,973 | NGUYEN ET AL. | |
| | Examiner | Art Unit | |
| | MONZER R. CHORBAJI | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**This final action is in response to the amendment received on 9/16/08**

**Claim Rejections - 35 USC § 102**

**1.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**2.** Claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatanaka (EP 0 321 908).

Regarding claim 21, Hatanaka discloses a vaporizer (figure 2:1) for vaporizing a liquid sterilant having non-vaporizable components therein (col.3, lines 18-19), the vaporizer comprising: a housing (figure 2:2 and 3) defining an inner space (unlabeled inner volume of the housing as shown in figure 2); and a core (the core is considered to be made up of structures 7, 9 and 10 as shown in figure 2) that is fully capable of being at least partially positioned within the inner space (unlabeled inner space within the housing as shown in figure 2) and removed from the inner space (col.4, lines 43-46, col.5, lines 19-20), wherein the core (the core is considered to be made up of structures 7, 9 and 10 as shown in figure 2) comprises: at least two fins (figure 2:9) extending toward the housing (figure 2:2 and 3) when the core is at least partially positioned within the inner space (unlabeled inner space within the housing as shown in figure 2); a circuitous flow path (see the arrows in figure 2) defined by the fins (figure 1:9 and 9A),

wherein the circuitous flow path is capable of causing the vaporized liquid sterilant to deposit a first portion of the non-vaporizable components on at least one of the fins (figure 2:9) and the housing (unlabeled inner wall of housing 3 next to the dished vaporization part 14 as shown in figure 2); and a recess (figure 2:7) defined in the core (figure 2:7, 9 and 10), wherein the recess (figure 2:7) is configured to receive at least a first portion of an outlet tube (the outlet tube is considered to be 10 and the rest of the tube that is not labeled as shown in figure 2) that is capable of being in a fluid communication with a sterilization chamber, the recess (7) comprising: an open end (unlabeled open end of 7); and a closed end (unlabeled back end of 7), wherein the first portion (considered as 10) of the outlet tube is configured to be positioned proximate to the closed end (unlabeled back end of 7) of the recess to create a flow restriction (unlabeled space between the back wall of 7 and the top of upper inner tube 10 is considered the flow restriction) for the vaporized liquid sterilant and thereby is capable of causing a second portion of the non-vaporizable components to deposit on one of walls of the recess (inner unlabeled back wall of 7) and the outlet tube (10).

Regarding claim 22, Hatanaka discloses an outlet tube (the outlet tube is considered to be 10 and the rest of the tube that is not labeled as shown in figure 2), wherein the outlet tube comprises an orifice plate (unlabeled upper portion of exhaust port 13 as shown in figure 1) having an orifice (unlabeled opening within exhaust port 13 as shown in figure 1) defined therethrough, wherein the orifice plate is configured to provide a second flow restriction (the second flow restriction is considered the flow

within the orifice, which has a smaller diameter than the unlabeled outlet tube above it).

Regarding claim 23, Hatanaka discloses an outlet tube (the outlet tube is considered to be 10 and the rest of the tube that is not labeled as shown in figure 2), wherein the outlet tube comprises a reducing section (considered the unlabeled inner diameter of tube 10 as shown in figure 10), and wherein the reducing section is configured to provide a second flow restriction (the flow within the unlabeled inner diameter of tube 10 is considered the second flow restriction).

***Claim Rejections - 35 USC § 103***

**3.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**4.** The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**5.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised

of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**6.** Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0 321 908).

Regarding claim 1, Cummings discloses a vaporizer (considered vaporizing chamber 10, its heating means as explained in col.3, lines 23-24 and passage 20) for vaporizing a sterilant from its liquid phase in a vapor phase sterilization system (col.2, lines 54-60) having a pressure below atmospheric pressure (col.3, lines 21-23), the vaporizer comprising: an inlet (12) configured to receive the sterilant in its liquid phase; an outlet (unlabeled outlet of passage 20 that is connected to sterilization chamber 22) configured to discharge the sterilant in its vapor phase; a flow restriction (20) between the inlet (12) and the outlet (unlabeled outlet of passage 20 that is connected to sterilization chamber 22), wherein the flow restriction (20) is capable of causing a second portion of the non-vaporizable ingredients to collect on a surface of the vaporizer prior to the vapor phase sterilant being admitted to a sterilization chamber (22); and a vacuum pump in fluid communication with the vaporizer (col.3, lines 29-31), wherein the vacuum pump is configured to create a vacuum within the vaporizer.

Cummings fails to teach the use of a removable core including a circuitous path, and wherein the circuitous path is configured whereby to collect a first portion of non-vaporizable ingredients of the sterilant. Hatanaka discloses a hydrogen peroxide

vaporizing apparatus (figure 2:1) having a removable (col.4, lines 43-46, col.5, lines 19-20) core (core is considered to be made up of structures 7, 9 and 10 as shown in figure 2) that comprises a circuitous flow path (see the arrows in figure 2) defined by the fins (figure 1:9 and 9A) in order to prevent the formation of large drops to generate sterilant with uniform density (col.4, lines 11-16). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus in Cummings with the removable core in order to prevent the formation of large drops to generate sterilant with uniform density as explained by Hatanaka (col.4, lines 11-16).

Regarding claim 5, Cummings discloses a vaporizer (considered vaporizing chamber 10, its heating means as explained in col.3, lines 23-24 and passage 20) for vaporizing a sterilant from its liquid phase in a vapor phase sterilization system (col.2, lines 54-60) having a pressure below atmospheric pressure (col.3, lines 21-23), the said vaporizer comprising: an inlet (12) configured whereby to receive the sterilant in its liquid phase; an outlet tube (unlabeled outlet of passage 20 that is connected to sterilization chamber 22) configured to discharge the sterilant in its vapor phase; a flow restriction (20) between the inlet and a portion of the outlet tube having an opening defined therein, and a vacuum pump (col.3, lines 29-31) in fluid communication with the vaporizer, wherein the vacuum pump is configured to create a vacuum within the vaporizer.

Cummings fails to teach the following: use of a removable core including a circuitous path, and wherein the circuitous path is configured whereby to collect a first portion of non-vaporizable ingredients of the sterilant; the flow restriction comprises an

orifice defined in an orifice plate positioned one of over an opening of the outlet tube and within the outlet tube; and the orifice includes having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice.

Hatanaka discloses a hydrogen peroxide vaporizing apparatus (figure 2:1) having a removable (col.4, lines 43-46, col.5, lines 19-20) core (core is considered to be made up of structures 7, 9 and 10 as shown in figure 2) that comprises a circuitous flow path (see the arrows in figure 2) defined by the fins (figure 1:9 and 9A) in order to prevent the formation of large drops to generate sterilant with uniform density (col.4, lines 11-16). In addition, Hatanaka discloses that the outlet tube comprises an orifice plate (unlabeled upper portion of exhaust port 13 as shown in figure 1) having an orifice (unlabeled opening within exhaust port 13 as shown in figure 1) positioned over an opening of the outlet tube, since the orifice provides an exhaust port for the sterilant (col.4, lines 19-23). As to the limitation that the orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice, Hatanaka discloses a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13) having an labeled inner orifice space connected to 10. Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice. Depending on the desired mixing and residence time within the apparatus, minimizing

or maximizing the cross-sectional area of the orifice would have been a matter of routine experimentation. The Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of at least a portion of the Hatanaka circuitous path and the flow restrictor in order to achieve the desired mixing time. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus in Cummings with the removable core in order to prevent the formation of large drops to generate sterilant with uniform density as explained by Hatanaka (col.4, lines 11-16).

Regarding claim 9, Cummings discloses a method of providing a vapor phase sterilant to a sterilization chamber (col.1, lines 12-16) comprising the steps of: creating temperature and pressure conditions within a vaporizer (col.3, lines 21-27) sufficient to vaporize the sterilant using a vacuum inducing device to lower the pressure within the vaporizer to a pressure below atmospheric pressure (col.3, lines 22-23); admitting the sterilant, in its liquid phase (col.2, lines 51-54), into the vaporizer and vaporizing the sterilant (col.2, lines 55-61); then passing the sterilant, in its vapor phase, through a flow restriction (18); and passing the sterilant, in its vapor phase, out of the vaporizer (col.2, lines 60-61). Cummings fails to teach passing the sterilant through a circuitous path; and collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path.

Hatanaka teaches passing the sterilant through a circuitous path (in figure 2, the circuitous path is made up of the unlabeled volume containing 14 and baffles 9 as indicated by the arrows). This is done to remove any liquid sterilant entrained within the vapor (see column 2, lines 34-42 and column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including the step of passing the sterilant through a circuitous path as taught by Hatanaka since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer.

Regarding claim 13, Cummings teaches a method of providing a vapor phase sterilant to a sterilization chamber (col.1, lines 12-16) comprising the steps of: creating temperature and pressure conditions within a vaporizer (col.3, lines 21-27) sufficient to vaporize the sterilant; using a vacuum inducing device to lower the pressure within the vaporizer to a pressure below atmospheric pressure (col.3, lines 22-23); admitting the sterilant, in its liquid phase, into the vaporizer (col.2, lines 51-54) and vaporizing the sterilant (col.2, lines 55-61); then passing the sterilant, in its vapor phase, through a flow restriction (18); and passing the sterilant, in its vapor phase, out of the vaporizer (col.2, lines 60-61). Cummings fails to teach passing the sterilant through a circuitous path; collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path; and wherein the step of passing the sterilant through the circuitous path comprises passing the sterilant through an orifice having a cross-

sectional area no greater than 44.1% of a cross- sectional area of the circuitous path immediately upstream of the orifice.

Hatanaka teaches passing the sterilant through a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9), then passing the sterilant through a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) and passing the sterilant out of the vaporizer (figure 1:13) since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer. Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation such that Hatanaka recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka circuitous path and the flow restrictor in order to achieve the desired mixing time. Regarding the disclosed percentage removal of the non-vaporizable components, Hatanaka teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of

removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including the step of passing the sterilant through a circuitous path as taught by Hatanaka since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer.

Regarding claim 17, Cummings discloses a method of providing a vapor phase sterilant to a sterilization chamber (col.1, lines 12-16) comprising the steps of: creating temperature and pressure conditions within a vaporizer (col.3, lines 21-27) sufficient to vaporize the sterilant; using a vacuum inducing device to lower the pressure within the vaporizer (col.3, lines 22-23) to a pressure below atmospheric pressure; admitting the sterilant, in its liquid phase, into the vaporizer (col.2, lines 51-54) and vaporizing the sterilant (col.2, lines 55-61); then passing the sterilant, in its vapor phase, through a flow restriction (18); and passing the sterilant, in its vapor phase, out of the vaporizer (col.2, lines 60-61). Cummings fails to teach passing the sterilant through a circuitous path; collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path; and wherein at least 75% of the non-vaporizable components are removed from the sterilant prior to the step of passing the sterilant out of the vaporizer.

Hatanaka teaches passing the sterilant through a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9), then passing the

sterilant through a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) and passing the sterilant out of the vaporizer (figure 1:13) since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer. Regarding the disclosed percentage removal of the non-vaporizable components, Hatanaka teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including the step of passing the sterilant through a circuitous path as taught by Hatanaka since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer.

Regarding claims 2-3 and 6, Cummings fails to teach the use of a circuitous path. Hatanaka teaches the use of a plurality of baffles (figure 2, the unlabeled volume containing baffles 9) where the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), since such a path results in a gas having a uniform density for improved surface sterilization by preventing the disinfectant gas from

carrying entrained drops out of the vaporizer (col.4, lines 39-40). Hatanaka further teaches that the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus in Cummings reference with the circuitous path since such a path results in a gas having a uniform density for improved surface sterilization by preventing the disinfectant gas from carrying entrained drops out of the vaporizer as explained by Hatanaka (col.4, lines 39-40).

Regarding claim 4, Cummings fails to teach the use of a circuitous path. Hatanaka discloses an apparatus having a circuitous path since such a path results in a gas having a uniform density for improved surface sterilization by preventing the disinfectant gas from carrying entrained drops out of the vaporizer (col.4, lines 39-40). Hatanaka further teaches that the apparatus includes a portion (figure 2, unlabeled space containing 9), which increases by at least 70% or more when compared with for example, structure10 in figure 2. Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan. Hatanaka recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. Thus, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art

at the time the invention was made to modify the dimensions of Hatanaka apparatus to provide a section of increased cross-sectional area in order to achieve the desired mixing time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus in Cummings reference with the circuitous path since such a path results in a gas having a uniform density for improved surface sterilization by preventing the disinfectant gas from carrying entrained drops out of the vaporizer as explained by Hatanaka (col.4, lines 39-40).

Regarding claims 7-8, Cummings discloses a flow restriction (18 or 20), but fails to teach or suggest retaining the sterilant vapor within the vaporizer. Hatanaka discloses a circuitous path having flow restrictions (figure 1:9A), because this path results in a gas having a uniform density for improved surface sterilization by preventing the disinfectant gas from carrying entrained drops out of the vaporizer (col.4, lines 39-40). Furthermore, the flow restriction (figure 1, 9A) of Hatanaka apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time (by varying the temperature and pressure through the vessel, one of ordinary skill would be able to vary the residence time in the vessel). The Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction in the Hatanaka apparatus in order to increase

residence time of the sterilant and thereby achieve the desired mixing time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus in Cummings reference with the circuitous path since such a path results in a gas having a uniform density for improved surface sterilization by preventing the disinfectant gas from carrying entrained drops out of the vaporizer as explained by Hatanaka (col.4, lines 39-40).

Regarding claims 15-16, Cummings discloses using liquid hydrogen peroxide (col.2, lines 51-53) such that water is a stabilizing compound for the liquid phase of the sterilant.

Regarding claims 10-12 and 14, Cummings reference fails to teach the following: passing the sterilant past a plurality of baffles, passing the sterilant in a first direction through an inner tube positioned concentrically within an outer tube, a second opposite direction between the inner tube and the outer tube, passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% and having the sterilant make at least two turns where each turn is at least 90 degrees.

Hatanaka discloses the following: passing the sterilant past a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion

(figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a passing the sterilant through a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer.

Regarding claim 18, Cummings discloses removing substantially all of the non-vaporizable components (51-60) from the sterilant prior to the step of passing the sterilant out of the vaporizer.

Regarding claims 19-20, Cummings fails to teach the step of retaining the sterilant within the vaporizer for at least 17 milliseconds or for at least 26 milliseconds. Hatanaka discloses a circuitous path having flow restrictions (figure 1:9A), because this path results in a gas having a uniform density for improved surface sterilization by preventing the disinfectant gas from carrying entrained drops out of the vaporizer (col.4, lines 39-40). Furthermore, the flow restriction (figure 1, 9A) of Hatanaka apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. Hatanaka recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time

depends on the dimensions of the flow restriction. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction of the Cummings reference in order to increase residence time of the sterilant and thereby achieve the desired mixing time as taught by the Hatanaka reference.

***Response to Arguments***

**7.** Applicant's arguments filed on 9/16/08 have been fully considered but they are not persuasive.

The amendment to the specification dated 9/6/08 has been accepted.

On pages 10-12 of the Remarks section; Applicant argues that Hatanaka teaches admitting the hot gas into the vaporizer decreases the concentration of the vaporized hydrogen peroxide which such teaching contradicts the teaching of Cummings to increase the concentration of hydrogen peroxide; and that the combination of Cummings and Hatanaka changes the principle of operation of Cummings.

The examiner disagrees with the characterization of the Hatanaka reference. Hatanaka uses hot gas not to decrease the concentration of vaporized hydrogen peroxide, but rather to generate sterilant gas having a uniform density for and not having entrained liquid droplets which would adversely affect the sterilization process. Clearly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka (‘908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) and

not having entrained liquid droplets which would adversely affect the sterilization process (col.4, lines 9-13).

***Conclusion***

**8.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

**9.** A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

**11.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**12.** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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